

AMENDMENTS TO THE CLAIMS

1-18. (Canceled)

19. (Currently Amended) The method of claim 74, wherein the advancing of the radioactive source into the catheter radiotherapy lumen is performed by advancing a source wire having [[said]] the radioactive source secured at its distal end.

20. (Previously Presented) The method of claim 19, wherein the source wire is a super-elastic source wire.

21. (Currently Amended) The method of claim 74, including selecting a radioactive source with a predetermined activity level, and setting [[said]] the predetermined time interval in which the radioactive source is positioned within [[said]] the region, to deliver a radiation dosage of from about 1,000 rads to about 1,500 rads to tissue in the vessel wall in proximity to the vessel lumen at the target site.

22. (Previously Presented) The method of claim 74, further removing the catheter from the vessel lumen after the radioactive source has been withdrawn.

23. (Canceled)

24. (Currently Amended) The method of claim 75, wherein the centering device is a balloon secured distally about the catheter with lobes forming channels along the distally secured portion, to position [[said]] the radiotherapy lumen at substantially the radial center of the lumen of the duct at [[said]] the site when the balloon is inflated for [[said]] the deployment.

25. (Canceled)

26. (Currently Amended) The method of claim 75, including advancing [[said]] the radioactive material into the radiotherapy lumen of the catheter on a super-elastic wire.

27. (Currently Amended) The method of claim 75, including designating ~~[[said]]~~ the predetermined radioactivity level and ~~[[said]]~~ the predetermined time interval to produce a radiation dosage of from about 1,000 rads to about 1,500 rads to tissue in the wall of the duct in proximity to the lumen of the duct at ~~[[said]]~~ the site.

28. (Currently Amended) A method of inhibiting stenosis at a target site in a blood vessel, which comprises:

inserting a longitudinally fluted balloon catheter into a vessel lumen until a target site is reached;

at the target site, radially centering a radiotherapy lumen having radioactive material of a predetermined radioactivity level by inflating the balloon wherein the radiotherapy lumen has been previously introduced at the target site and wherein the balloon is configured to permit blood flow past the inflated balloon without dilating the lumen of the vessel;

~~introducing radioactive material of predetermined radioactivity level at substantially the radial center of the lumen of the vessel at said site through a radiotherapy lumen of a longitudinally fluted balloon catheter previously inserted into the vessel lumen and whose balloon has then been inflated for radially centering said radiotherapy lumen at said site and permitting blood flow past the inflated balloon without dilating the lumen of the vessel;~~

leaving ~~[[said]]~~ the radioactive material substantially centered in the vessel lumen, while perfusion is allowed through the vessel lumen, at ~~[[said]]~~ the site for a predetermined period of time; and

immediately after ~~[[said]]~~ the time period expires, removing the radioactive material from the site.

29. (Canceled)

30. (Currently Amended) The method of claim 28, including introducing the radioactive material through ~~[[said]]~~ the radiotherapy lumen of the balloon catheter in a manner to maintain the radioactive material confined at substantially the radial center of the lumen of the vessel at ~~[[said]]~~ the site.

31. (Currently Amended) The method of claim 30, wherein [[said]] the radioactive material is confined within the distal end of a wire configured to enable rapid travel through the radiotherapy lumen of [[said]] the balloon catheter to the target site.

32. (Currently Amended) The method of claim 30, wherein [[said]] the predetermined radioactivity level and [[said]] the predetermined time period are computed to achieve delivery of from about 1,000 rads to about 1,500 rads to tissue in the wall of the duct in proximity to the lumen of the duct at [[said]] the site.

33. (Currently Amended) A method of inhibiting restenosis in a blood vessel at a narrowed region of the lumen thereof to be treated by an angioplasty procedure, which comprises:

performing the angioplasty procedure;

substantially immediately thereafter, introducing radioactive material of predetermined radioactivity level through a balloon catheter for a predetermined interval of treatment time, during which perfusion is allowed by a centering device with longitudinally disposed channels, at substantially the radial center of the lumen of the blood vessel along [[said]] the narrowed region at which [[said]] the angioplasty procedure was performed, wherein the centering device centers the radioactive material without dilating the lumen of the blood vessel; and

removing [[said]] the radioactive material from the blood vessel after [[said]] the treatment time interval has elapsed.

34. (Currently Amended) The method of claim 33, ~~including further comprising,~~ maintaining [[said]] the radioactive material at substantially the radial center of the vessel lumen at [[said]] the region for the entirety of [[said]] the treatment time interval without blocking the flow of blood through the vessel along [[said]] the region.

35. (Currently Amended) The method of claim 34, ~~including further comprising,~~ introducing and maintaining [[said]] the radioactive material at substantially the radial center of the vessel lumen at [[said]] the region thereof through a radiotherapy lumen of a balloon catheter inserted

into the vessel lumen and with its balloon inflated at [[said]] the region to form lobes adjacent the longitudinal channels for both the radial centering and blood flow.

36. (Currently Amended) The method of claim 35, ~~including further comprising~~, conveying the radioactive material through [[said]] the radiotherapy lumen of the balloon catheter by means of an elongate member.

37. (Currently Amended) The method of claim 33, ~~including further comprising~~, establishing [[said]] the predetermined radioactivity level and [[said]] the predetermined treatment time interval to result in the delivery of a prescribed dosage of radiation to tissue in the vessel wall in [[said]] the region.

38. (Currently Amended) A therapeutic process for alleviating hyperplasia in a body duct, ~~which comprises~~comprising:

centering source material of predetermined radioactivity level within a therapy lumen by inflating a centering device, wherein the centering device is positioned at a preselected site within a lumen of a body duct;

irradiating the wall of the duct with the source material; while allowing perfusion through the duct, ~~with source material of predetermined radioactivity level positioned at substantially the radial center of the lumen of the duct by a centering device at a preselected site~~, wherein the centering device is a fluted balloon capable of centering the source material without dilating the duct; and

immediately after a predetermined period of irradiation has elapsed, removing the source material from [[said]] the site.

39. (Currently Amended) The method of claim 38, including performing [[said]] the irradiation with [[said]] the source material contained within [[a]] the therapy lumen of a balloon catheter inserted into the lumen of the duct and with its balloon shaped when inflated at [[said]] the site to ~~form radial centering channels for center~~[[said]] the therapy lumen.

40. (Currently Amended) A therapeutic process for alleviating hyperplasia in a fluid-carrying duct of a patient's body, ~~which comprises~~ comprising:

radially centering source material of predetermined radioactivity level within a therapy lumen by inflating a centering device, wherein the centering device is positioned at a preselected site which has been subjected to trauma within a lumen of a fluid-carrying duct;

~~irradiating the wall of the duct with source material of predetermined radioactivity level positioned at substantially the radial center of the lumen of the duct by a centering device at a preselected site which has been subjected to trauma,~~ while concurrently allowing passage of fluid through the duct past the position of the source material, wherein the centering device is a fluted balloon capable of centering the source material without dilating the duct; and

immediately after a predetermined period of irradiation has elapsed, removing the source material from ~~[[said]]~~ the site.

41. (Currently Amended) The method of claim 40, wherein irradiating the duct wall is performed by first inserting into the lumen of the duct a balloon catheter whose balloon is shaped to form inflation lobes along the catheter adapted to substantially radially center a lumen of the catheter when the balloon is inflated in the duct, positioning and then inflating ~~[[said]]~~ the balloon at ~~[[said]]~~ the site for ~~[[said]]~~ the centering of the catheter lumen and to allow passage of fluid through channels between ~~[[said]]~~ the lobes past the inflated balloon at ~~[[said]]~~ the site, and thereafter conveying ~~[[said]]~~ the source material through ~~[[said]]~~ the catheter lumen to ~~[[said]]~~ the site.

42. (Currently Amended) The method of claim 41, including conveying ~~[[said]]~~ the source material through ~~[[said]]~~ the catheter lumen to ~~[[said]]~~ the site on a super-elastic wire adapted to navigate curves in a path through the catheter lumen created by the duct.

43. (Currently Amended) The method of claim 42, further including deflating and withdrawing ~~[[said]]~~ the balloon catheter from the lumen of the duct after ~~[[said]]~~ the removal of the source material.

44. (Currently Amended) An angioplasty procedure ~~which comprises~~ comprising:
opening a narrowed region in the lumen of a blood vessel of a patient to increase blood flow therethrough;
thereafter, irradiating the wall of the vessel with a source of predetermined radioactivity level, the irradiating comprising:
radially centering a centering catheter by inserting into the lumen of the vessel the centering catheter wherein the centering catheter includes a distal portion of its length sized and shaped to substantially radially center a lumen within the catheter while allowing passage of blood at the previously narrowed region and without dilating the vessel,
halting insertion of the centering catheter when the distal portion thereof is situated at the previously narrowed region, and
delivering the radioactive source through the catheter lumen to a desired location along the distal portion thereof;
~~positioned at substantially the radial center of the opened lumen along the previously narrowed region by a centering device, while concurrently allowing passage of blood through the vessel past the site of the radioactive source, wherein the centering device centers the source without dilating the vessel;~~ and
after completing a predetermined period of irradiation, removing ~~[[said]]~~ the source from the vessel.

45. (Cancelled).

46. (Currently Amended) The angioplasty procedure of claim ~~[[45]]~~ 44, including delivering ~~[[said]]~~ the radioactive source through ~~[[said]]~~ the catheter lumen ~~[[on]]~~ confined within a super-elastic wire.

47. (Currently Amended) The method of claim ~~[[45]]~~ 44, further including withdrawing ~~[[said]]~~ the centering catheter from the vessel lumen after removal of the radioactive source from the vessel.

48. (Currently Amended) A method of inhibiting stenosis at a target site in a coronary artery of a patient's body, ~~which comprises~~ comprising:

inserting a radiation catheter with a distally secured longitudinally fluted centering balloon through a portion of the patient's cardiovascular system until ~~the~~ the balloon is at ~~the~~ the target site;

inflating ~~the~~ the balloon to substantially align a radiotherapy lumen of ~~the~~ the catheter with the longitudinal axis of the coronary artery at ~~the~~ the target site while securing ~~the~~ the catheter thereat and enabling blood flow past the inflated balloon through longitudinal flutes thereof, wherein ~~the~~ the balloon, when inflated, centers a radioactive distal tip without dilating ~~the~~ the target site;

advancing a distal tip of a dummy wire through the radiotherapy lumen of the catheter to ~~the~~ the target site, from a delivery apparatus coupled to the proximal end of ~~the~~ the catheter, and retracting the dummy wire back into the delivery apparatus while retaining a measurement of the distance traveled by the distal tip of the dummy wire to reach ~~the~~ the target site;

advancing the radioactive distal tip of a source wire of predetermined radioactivity level from ~~the~~ the delivery apparatus through the radiotherapy lumen of the catheter the same distance traveled by the distal tip of the dummy wire for positioning at ~~the~~ the target site;

retracting the source wire back into the delivery apparatus after a predetermined time interval has elapsed with the radioactive tip of the source wire positioned at the target site; and

deflating ~~the~~ the balloon and removing the radiation catheter from the patient's body.

49. (Previously Presented) The method of claim 48, including using a super-elastic material for all but the radioactive portion of the source wire.

50. (Previously Presented) The method of claim 49, including selecting a nickel-titanium alloy as the super-elastic material.

51. (Currently Amended) The method of claim 48, wherein the source wire is retracted to a radiation-proof safe in ~~the~~ the delivery apparatus.

52. (Currently Amended) The method of claim 48, including inserting ~~[[said]]~~ the radiation catheter over a guide wire previously inserted into the cardiovascular system at least as far as the target site in the coronary artery, and

keying the coupling of the proximal end of the catheter to ~~[[said]]~~ the delivery apparatus to restrain the catheter and guide wire from undergoing rotation in the cardiovascular system during performance of the method.

53. (Currently Amended) The method of claim 48, including predetermining values of ~~[[said]]~~ the predetermined radioactivity level and ~~[[said]]~~ the predetermined time interval to result in delivery of a dose of radiation in a range from about 1,000 rads to about 1,500 rads to tissue in the coronary artery wall in proximity to the radioactive tip at the target site prior to retracting the source wire therefrom.

54. (Currently Amended) A method of inhibiting stenosis at a target site in a blood vessel, ~~which comprises~~comprising:

introducing a radiation catheter, having a radiotherapy lumen with a proximal opening and a distal sealed end and having a channeled centering balloon located on the catheter for placement adjacent the target site, over a guide wire into the lumen of the blood vessel until ~~[[said]]~~ the centering balloon is positioned at the target site;

inflating ~~[[said]]~~ the centering balloon through an inflation lumen of the radiation catheter wherein inflating the centering balloon substantially radially centers the radiotherapy lumen of the radiation catheter to position ~~[[said]]~~ the radiotherapy lumen of the catheter at substantially the radial center of the vessel lumen at the target site and ~~to allow~~ allows perfusion of blood past the inflated centering balloon through channels formed thereby, and wherein the inflated centering balloon centers the radioactive source without dilating the target site;

advancing a source wire having a distal radioactive source of predetermined activity through ~~[[said]]~~ the radiotherapy lumen of the catheter from the proximal opening thereof until the radioactive source is within a region of the inflated centering balloon at the target site; and

withdrawing the source wire from ~~[[said]]~~ the radiotherapy lumen of the catheter at the end of a predetermined time interval of ~~[[said]]~~ the radioactive source being positioned at the target site.

55. (Previously Presented) The method of claim 54, including selecting a super-elastic material for the non-radioactive portion of the source wire.

56. (Previously Presented) The method of claim 55, including selecting a nickel-titanium alloy as the super-elastic material.

57. (Currently Amended) The method of claim 54, including:
coupling the proximal end of the radiation catheter to an afterloader, and wherein the source wire is retracted to a storage location in [[said]] the afterloader.

58. (Currently Amended) The method of claim 57, including:
threading the guide wire through a guide wire lumen of the radiation catheter eccentrically offset relative to [[said]] the radiotherapy lumen as part of the introducing of the radiation catheter over the guide wire, and
keying the coupling of the proximal end of the radiation catheter to the afterloader to restrain the catheter and guide wire from undergoing rotation in the blood vessel during performance of the method.

59. (Currently Amended) The method of claim 54, wherein [[said]] the predetermined activity level of the radioactive source and [[said]] the predetermined time interval in which the radioactive source is positioned at the target site are calculated to enable delivery of a dose of radiation in a range from about 1,000 rads to about 1,500 rads to tissue in the vessel wall in proximity to the vessel lumen at the target site.

60. (Canceled)

61. (Currently Amended) A method of treating the wall of a blood vessel, comprising:
advancing a guidewire to a treatment site in the blood vessel;
advancing a catheter having a guidewire lumen over the guidewire to the treatment site;

advancing a radioactive source through a working lumen of the catheter, the distal end of the working lumen being located proximal to the distal tip of the catheter, and

using a centering catheter having an inflatable centering balloon with channels for enabling both the radial centering of the inflatable centering balloon and blood flow past the catheter as [[said]] the catheter to maintain the radioactive source at substantially the radial center of the lumen of the blood vessel after advancement of the source to the treatment site.

62. (Currently Amended) The method of claim 61, including using a centering catheter with at least one passageway for adequate blood flow through the vessel while [[said]] the radioactive source is maintained at substantially the radial center of the vessel lumen.

63. (Cancelled).

64. (Currently Amended) A method as in claim 74 wherein [[said]] the balloon, when inflated, centers [[said]] the radiotherapy lumen without dilating the vessel lumen.

65. (Previously Presented) A method as in claim 75 wherein the centering device, when deployed, does not dilate the lumen of the duct.

66. (Canceled)

67. (Currently Amended) A method of treating a body duct with a centering catheter from within the lumen of the duct, which comprises:

inserting the centering catheter into the lumen of the body duct to position a centering device of [[said]] the catheter at a site of the duct to be treated;

deploying [[said]] the centering device of the catheter to position a radiotherapy lumen of the catheter [[at]] to substantially [[the]] ~~radial-radially~~ center the radiotherapy lumen of the catheter in [[of]] the lumen of the duct at [[said]] the site;

advancing material having a predetermined level of radioactivity into [[said]] the radiotherapy lumen of the catheter to a position at [[said]] the site;

retracting [[said]] the radioactive material after a predetermined time interval at [[said]] the site, wherein the centering device, when deployed, does not dilate the lumen of the duct.

68-73. (Canceled)

74. (Previously Presented) A method of treating the wall of a blood vessel from within a lumen thereof, with a radiation catheter including a radiotherapy lumen, a longitudinally channeled distal balloon, and a balloon inflation lumen, the method comprising:

inserting the catheter into the vessel lumen until the balloon is adjacent a target site of the vessel wall to be treated, wherein the inserting of the catheter into the vessel lumen is performed by steering the catheter over a guide wire previously inserted into the vessel lumen past the target site;

inflating the balloon to substantially center the catheter radiotherapy lumen within the vessel lumen at the target site while allowing perfusion of blood past the inflated balloon through channels formed thereby;

advancing a radioactive source into the catheter radiotherapy lumen to position the source within a region thereof along a portion of the catheter occupied by the balloon; and

withdrawing the source after being positioned within the region for a predetermined interval of time.

75. (Previously Presented) A method of treating a body duct with a centering catheter from within a lumen of the duct, comprising

inserting the centering catheter into the lumen of the body duct over a guidewire previously inserted therein to position a centering device of the catheter at a site of the duct to be treated;

deploying the centering device of the catheter to position a radiotherapy lumen of the catheter at substantially the radial center of the lumen of the duct at the site, the centering device allowing perfusion while the centering device is deployed;

advancing material having a predetermined level of radioactivity into the radiotherapy lumen of the catheter to a position at the site; and

retracting the radioactive material after a predetermined time interval at the site.